

Attorney Docket No.: DEX-0199
Inventors: Salceda et al.
Serial No.: 09/817,318
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REMARKS

Claims 1 and 3-6 are pending in the instant application. Claims 1 and 3-6 have been rejected. Claims 1, 5 and 6 have been amended. Support for these amendments is provided in the specification at page 1, lines 12-15, page 16, lines 24-27, page 18, line 8-15 and in the Examples beginning at page 50. Thus, no new matter is added by these amendments. Reconsideration is respectfully requested in light of these amendments and the following remarks.

I. Sequence Rule Compliance

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The Examiner suggests that the application contains sequence disclosures that are encompassed by the definition for nucleotide and/or amino acid sequences set forth in 37 C.F.R. 1.821(a)(1) and (a)(2) which are not in the Sequence Listing. Specifically, the Examiner suggests that the amino acid sequence in claim 1 is not accompanied by a sequence identification number.

It is respectfully pointed out, however, that claim 1 has been amended to delete any reference to this unnumbered amino acid sequence.

Thus, the application and the Sequence Listing are in compliance with the requirements of 37 C.F.R. 1.821-25.

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II. Rejection of Claims 1 and 3-6 under 35 U.S.C. 112, first paragraph - Written Description

Claims 1 and 3-6 have been rejected under 35 U.S.C. § 112, first paragraph, for lack of clear written description with respect to a fragment of SEQ ID NO:1 and a nucleic acid sequence with 95% identity to an antisense of SEQ ID NO:1. Specifically, the Examiner suggests that a fragment of SEQ ID NO:1 encoding a 15 to 139 amino acid sequence encompasses unrelated polynucleotide sequences with unknown structure, function and length, provided they share with SEQ ID NO:1 a fragment that encodes a 15 to 139 amino acid sequence. Further, the Examiner suggests that a nucleic acid sequence with 95% identity to an antisense sequence of SEQ ID NO:1 encompasses variants of SEQ ID NO:1 having any type of substitution without any limit on the number of substitutions and without any common structural or functional attribute identified.

Accordingly, in an earnest effort to advance the prosecution of this case, Applicants have amended the claims to delete any reference to fragments of SEQ ID NO:1. Further, Applicants have clarified in part (c) (now part (b) as amended) a functional attribute as being upregulated in or specific to human mammary

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gland cancer tissue as well as the structural attribute of sharing 95% identity with the antisense sequence of SEQ ID NO: 1 and. Support for these amendments is provided in the specification at page 1, lines 12-15, page 16, lines 24-27, and page 18, line 8-15. Further, methods for assessing upregulation and specificity of a polynucleotide with 95% identity to the antisense sequence of SEQ ID NO:1 are set forth in the Examples beginning at page 50.

Thus, contrary to the Examiner's suggestion, the disclosure does describe common attributes or characteristics that identify members of the claimed polynucleotide sequence with 95% identity to an antisense of SEQ ID NO:1. Further, the claims, as amended set forth this characteristic and thus are commensurate in scope with the written description so that one of skill in the art can recognize that Applicants invented what is claimed.

Accordingly, the claims as amended meet the written description requirements of 35 U.S.C. § 112, first paragraph and withdrawal of this rejection is respectfully requested.

III. Rejection of Claims 1, and 3-6 under 35 U.S.C. § 112, first paragraph - Lack of Enablement

Claims 1 and 3-6 have been rejected under 35 U.S.C. § 112,

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first paragraph, for lack of enablement for a fragment of SEQ ID NO:1 encoding a 15 to 139 amino acid sequence.

Thus, in an earnest effort to advance the prosecution of this case, Applicants have canceled this phrase from the claims. Withdrawal of this rejection under 35 U.S.C. § 112, first paragraph, is respectfully requested.

Claims 1 and 3-4 have also been rejected under 35 U.S.C. § 112, first paragraph, for lack of enablement with respect to a nucleotide sequence with 95% identity to SEQ ID NO:1. The Examiner suggests that a nucleic acid sequence with 95% identity to an antisense sequence of SEQ ID NO: encompasses numerous structural variants not shown by Applicants to be capable of functioning as that which is being disclosed.

Accordingly, in an earnest effort to advance the prosecution of this case, Applicants have amended the claims to be drawn to a nucleic acid sequence with 95% identity to an antisense sequence of SEQ ID NO: 1 and which is upregulated in or specific to human mammary gland cancer tissue. Support for these amendments can be found in the specification at page 1, lines 12-15, page 16, lines 24-27, and page 18, line 8-15.

The test for enablement as set forth in MPEP § 2164.01 is whether one reasonably skilled in the art could make and use the

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invention from the disclosure in the patent coupled with information known in the art without undue experimentation. One of skill in the art can routinely identify nucleic acid sequences with 95% identity to SEQ ID NO:1 based upon the nucleic acid sequence for SEQ ID NO:1 taught in the instant application coupled with well known methods for assessing % identity such as set forth in standard reference texts such as Sambrook et al. 1989 (Molecular Cloning, A Laboratory Manual, 2nd Edition, Cold Spring Harbor Press, Cold Spring Harbor). The experimentation required to identify a nucleic acid sequence with 95% identity to SEQ ID NO:1 would therefore not be considered undue.

Further, detailed methods for assessing upregulation and/or specificity of a polynucleotide sequence in human mammary gland cancer tissue are taught in the specification beginning at page 50. Clearly, the experimentation required to identify those polynucleotides of the claimed invention with 95% identity which are then upregulated or specific to human mammary gland cancer tissue cannot be considered undue when the specification provides such detailed guidance with respect to the direction in which this experimentation should proceed. See MPEP § 2164.06.

Withdrawal of this rejection under 35 U.S.C. § 112, first paragraph, is therefore respectfully requested in light of the

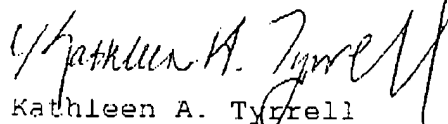
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amendments to the claims and the above remarks.

IV. Conclusion

Applicants believe that the foregoing comprises a full and complete response to the Office Action of record. Accordingly, favorable reconsideration and subsequent allowance of the pending claims is earnestly solicited.

Respectfully submitted,


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